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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,827	01/24/2001	Robert Schlegel	MRI-007A	2603

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
SHEINBERG, MONIKA B	
ART UNIT	PAPER NUMBER
1634	9

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,827	SCHLEGEL ET AL.	
	Examiner	Art Unit	
	Monika B Sheinberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-6, 10-21, 23-26, 44, 46-49, and 51-53, drawn to a method of detecting prostate cancer using nucleic acids, classified in class 435, subclass 6. *(If this group is elected, please see sequence election requirement further below).*

II. Claims 1, 2, 4-9, 15-22, 24-26, 44, 45, 47-50, 52 and 53, drawn to a method of detecting prostate cancer using polypeptides, classified in class 435, subclass 7.1. *(If this group is elected, please see sequence election requirement further below).*

III. Claims 27-32, 35, 39 and 40, drawn to a method of selecting compositions that inhibit or promote prostate cancer by altered expression analysis, classified in class 514, subclass 2. *(If this group is elected, please see sequence election requirement further below).*

IV. Claims 33-35 and 40, drawn to isolated nucleic acids, classified in class 536, subclass 23.1. *(If this group is elected, please see sequence election requirement further below).*

V. Claims 33, 35 and 40, drawn to isolated polypeptides, classified in class 530, subclass 350. *(If this group is elected, please see sequence election requirement further below).*

VI. Claims 33, 35-38 and 40, drawn to an antibody and compositions containing the same, classified in class 424, subclass 130.1. *(If this group is elected, please see sequence election requirement further below).*

VII. Claim 41-43, drawn to a method of treatment by altering gene expression, classified in class 514, subclass 44. *(If this group is elected, please see sequence election requirement further below).*

VIII. Claims 54 and 55, drawn to a computerized method and system for identifying a prostate cancer cell, classified in class 702, subclass 19. *(If this group is elected, please see sequence election requirement further below).*

It is noted that several claims may appear in more than one group. The claim will be examined to the extent that the claim is directed to the elected subject matter. For example, claims 33, 35 and 40 are so broad that depending on whether the compounds

and reagents include nucleic acids, polypeptides, and/or antibodies, the claim would be examined to the extent that the claim reads upon the elected group.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (I, IV, VII and VII); Groups (II and V); and Group VI are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I, IV, VII and VII, the critical feature is a polynucleotide; for Groups II and V, the critical feature is a polypeptide; for Group VI, the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of the above Groups to be directed as to its synthesis by a polynucleotide of the above Groups, however, the completely separate chemical types of the inventions of the polynucleotide, peptide, and antibody Groups supports the undue search burden if both were examined together. Additionally, polynucleotides, polypeptides, and antibodies have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings of (I, IV, VII and VII); (II and V); (VI) are independent and/or distinct invention types for restriction purposes.

The inventions of Groups I and (V, VI) are patentably distinct inventions because the polypeptides and antibodies of Groups V and VI are not relied upon in the method of Group I. Instead, Group I uses nucleic acids. Therefore, the inventions are novel and unobvious over one another.

The inventions of Groups II and (IV, VI) are patentably distinct inventions because the nucleic acids and antibodies of Groups IV and VI are not relied upon in the method of Group II. Instead, Group II uses proteins. Therefore, the inventions are novel and unobvious over one another.

The inventions of Groups (III, VII) and (IV, V, VI) are patentably distinct inventions because the nucleic acids, polypeptides and antibodies of Groups IV, V and VI are not relied

upon in the methods of Groups III and VII. Instead, Group III uses compositions (test compounds), while VII uses antisense. Therefore, the inventions are novel and unobvious over one another.

The inventions of Groups I, II, III and VII are patentably distinct methods because each have different objectives, different uses, different reagents and different steps in methodology. Therefore the methods are distinct over one another.

The inventions of Groups VIII and (I, II, III, VII) are patentably distinct because data processing method of Group VIII that requires systems and tools that allow for querying data files of a database are not relied upon in Groups I, II, III and VII. Groups I, II, III and VII do not carry the requirement of creating a data file and query, or utilizing a database and server. Therefore the methods are distinct over one another.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For example, an elected Group drawn to amino acid sequences, the Applicant(s) must further elect a single amino acid sequence. For an elected Group drawn to nucleic acid sequences, the Applicant(s) must elect a single nucleic acid sequence (See MPEP 803.04). **It is noted that this is a restriction requirement to a single sequence and NOT a specie election requirement.**

MPEP 803.04 states:

> "Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions

of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Examination will be restricted to only the elected sequence.

Conclusion

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday (except Wednesday) from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 21, 2003

Monika B. Sheinberg
Art Unit 1634

MBS

Jehanne Souaya

JEHANNE SOUAYA
PATENT EXAMINER

3/24/03